

PATENT COOPERATION TREATY

REC'D 04 APR 2005

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From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) **01 APR 2005**

Applicant's or agent's file reference

FOR FURTHER ACTION

See paragraph 2 below

NIVA/001 PCT

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/IL04/00071

25 January 2004 (25.01.2004)

23 January 2003 (23.01.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61K 9/00, 47/00, 9/68, 9/48, 9/14 and US Cl.: 424/400, 439, 440, 441, 451, 464, 489; 514/819, 820, 925

Applicant

SHAPIRA, NIVA

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☐ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

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**WRITTEN OPINION OF THE
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International application No.

PCT/IL04/00071

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language ____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

V.1. Reasoned Statements:

The opinion as to Novelty was positive (Yes) with respect to claims 4, 8, 14-17, 24, 28, 34-37, 39, 51-52, 57-60
The opinion as to Novelty was negative (No) with respect to claims 1-3, 5-7, 9-13, 18-23, 25-27, 29-33, 38-50, 53-56, 61-62
The opinion as to Inventive Step was positive (Yes) with respect to claims NONE
The opinion as to Inventive Step was negative (NO) with respect to claims 1-62
The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-62
The opinion as to Industrial Applicability was negative (NO) with respect to claims NONE

V. 2. Citations and Explanations:

Claims 1-3, 9-13, 18-23, 29-33, 38, and 40-42 lack novelty under PCT Article 33(2) as being anticipated by US patent 5,708,017.

US '017 disclose an oral paste containing 220 g omeprazole, 0.01g BHT (antioxidant), potassium sorbate (basifying agent), and an oily liquid vehicle. See example 5.

Claims 1-3, 5-7, 10-13, 18-23, 25-27, 30-33, 38, 40-50, 53-56, and 61-62 lack novelty under PCT Article 33(2) as being anticipated by US patent 6,284,265.

US '265 discloses an antacid formulation containing calcium carbonate and dicalcium phosphate in an amount of 11-45%, 0.02-1% antioxidants and 46-84.5% of a carrier. See claims and column 2, lines 15-55.

Claims 8-9, 28-29, 51-52 lack an inventive step under PCT Article 33(3) as being obvious over US patent 6,284,265 in view of US patent 5,935,600.

US '265 discloses an antacid formulation containing calcium carbonate and dicalcium phosphate in an amount of 11-45%, 0.02-1% antioxidants and 46-84.5% of a carrier. See claims and column 2, lines 15-55.

US '265 does not teach the instant antacids.

US '600 teaches the use of calcium carbonate or another antacid in conjunction with an anti-ulcerative agent such as cimetidine, famatidine, omeprazole, or rantidine.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of US '261 and '600 and formulate the instant antacid composition. One would have been motivated to do so since US '600 teaches the effectiveness of the combination of an antacid and an anti-ulcerative agent. Therefore, the invention is prima facie obvious.

Claims 1-62 lack an inventive step under PCT Article 33(3) as being obvious over US patent 4,806,354.

Green teaches a composition containing antacids, antioxidants, prostaglandin, and conventional excipients.

Green does not specify the concentration of each active.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to manipulate the concentrations

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In case the space in any of the preceding boxes is not sufficient.

taught by the prior art during routine experimentation. One would have been motivated to do so to obtain the best possible results.

Claims 1-62 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry, i.e. the pharmaceutical industry.

Claims 4, 8, 14-17, 24, 28, 34-37, 39, 51-52, and 57-60 meet the criteria set out in PCT Article 33(2) because the prior art does not teach or fairly suggest the instant dependent limitations.